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25 August,
1998

Dockets Management Branch (HFA-305)
Food & Drug Administration
ATTN:
DOCKET #98-0044
C/o Dr. Michael Friedman, MD
Lead Deputy Commissioner
5630
Fishers Lane, Rm. 1061
Rockville, MD 20857-0001

Dear Dr. Friedman:

I
totally and emphatically SUPPORT FDA's EFFORT to fully implement DSHEA as intended by the 1994 Congress, but I strongly object to what I understand are proposed regulations which will:
1. limit my and everyone's access to
information about dietary supplements and health, and 2. redefine "disease", restricting my and everyone's ability to focus on preventative care and wellness. I feel strongly any final FDA rules must fall within the true meaning and intent of the 1994 DSHEA as MANDATED by CONGRESS.

Is the FDA
PROPOSING yet ANOTHER RULE on "structure/function claims", 21 CFR Part 101/Docket #98N-0044, when the 1994 Congress set adequate conditions in place in the DSHEA? Is the FDA tampering with Section 6 of DSHEA to restrict potent educational information access by the American people? I am vehemently opposed to any changes in Section 6 of DSHEA. Americans deserve free access to

available health promoting information. FDA's proposed rulemaking is totally unacceptable to me as an American consumer of dietary supplements.

Why
another attempt to thwart American freedom and congressional direction? Congress enacted the Dietary Supplement Health and Education Act of 1994 (DSHEA) for some very specific purposes, i.e. to regulate yet protect the health food industry and nutritional supplements, and the ability of Americans to choose for themselves. It is my understanding FDA is proposing NEW RULES which will take effect THIS COMING Thursday, August 27, 1998. Are these rules counterproductive to the mandates of DSHEA of 1994?

It is my understanding FDA's new rules
would totally circumvent the 1994 DSHEA's provisions by:
1. Expanding the
definition of the word "disease" to include terms referring to normal conditions such as menopause, aging, PMS, headache, pregnancy and the like. Under FDA's proposal ANY deviation from a "normal" state would be considered a "disease". Under FDA regulations, ANY claim having reference to this NEW definition of "disease" is therefore AUTOMATICALLY a "DRUG" claim. Consequently, ANY claim made by a dietary supplement is AUTOMATICALLY illegal under FDA's drug regulations! Why?
2. In 1994 FDA tried to restrict "structure/function"
labeling claims on supplements by limiting the claims to only "normal" conditions, but Congress intentionally took the word "normal" out. FDA's NEW IMPROVED regulations are putting the word "normal" right back in! Why? 3. Under the two aforementioned rule changes, even mere titles of customer informational brochures on store shelves which simply mention diseases would give the FDA enough reason to take products and educational information off store shelves. Why?

The strongest feature of the DSHEA of 1994 is its'
"structure/function" provisions regarding claims on dietary supplement labels which inform consumers what a particular product might do for them. Clearly, the "structure/function" information has made a tremendous difference to consumers. DSHEA allows products to make "structure/function" claims on product labels. Redefining the word "disease" in a way that limits such health information is unacceptable and the proposal must be withdrawn. I want free access to available information about dietary supplements and health, which DSHEA provides for me.

In 1994 the FDA made a hard fought effort to strangle
the "health food" industry and individual Americans' right to choose dietary supplements for themselves. Elimination of personal choice to PREVENT illness and disease through educated use of dietary supplements such as vitamins, minerals, herbs and other health promoting food products appeared to be FDA's MAIN GOAL. Congress intervened on behalf of their constituent's, and the will of the people, and MANDATED what the FDA was to abide by. Yet here we are, four years later, same song, second verse, if the FDA couldn't legislate away the right to nutritional supplements they are attempting to regulate away constitutionally guaranteed rights to freedom of choice by the American people. WHY, WHY, WHY, WHY, WHY?

Any help you might afford in consideration and
prevention of tampering with my right to choose health, wellness and disease

prevention would be sincerely appreciated. I look forward to your reply at your earliest convenience.

Sincerely,

Stephanie Licht